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| APPLICATION NO.         | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|-------------|----------------------|---------------------|------------------|
| 10/678,805              | 10/03/2003  | Madhavi Krishnan     | UM-07718            | 3256             |
| 7590                    | 12/08/2005  |                      |                     |                  |
|                         |             |                      | EXAMINER            |                  |
|                         |             |                      | WILDER, CYNTHIA B   |                  |
|                         |             |                      | ART UNIT            | PAPER NUMBER     |
|                         |             |                      | 1637                |                  |
| DATE MAILED: 12/08/2005 |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                          |                     |  |
|------------------------------|--------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b>   | <b>Applicant(s)</b> |  |
|                              | 10/678,805               | KRISHNAN ET AL.     |  |
|                              | <b>Examiner</b>          | <b>Art Unit</b>     |  |
|                              | Cynthia B. Wilder, Ph.D. | 1637                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 11 October 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 9-13 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-8 and 14-31 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/11/05.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

1. Applicant's election without traverse of Group I, claims 1-8 and 14-31 in the reply filed on September 14, 2005 is acknowledged. Claims 9-13 are withdrawn from consideration as being drawn to a non-elected invention

Applicant's preliminary amendment filed on May 10, 2004 and December 12, 2004 is acknowledged and has been entered.

### ***Specification***

2. The use of the trademark "Plexiglas" has been noted throughout this application and in the claims 5, 18 and 28. It should be *capitalized* wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claim 22 is indefinite at the recitation of "less than about" because the term "less than about" is not defined by the claim, the specification does not provide a standard for ascertaining

the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-8 and 14-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Burns et al (US 6,048,734, April 11, 2000). Note\* It is noted that the specification at paragraph 0014 does not provide a limiting definition of what is meant by "active or passive cooling means", but rather only provides an example. Accordingly, the preceding rejection is based on the Examiner's broad interpretation of the claim language. Regarding claims 1 and 14, Burns et al teach a method comprising providing a reaction vessel, a heat source, an active cooling means and reactants; introducing said reactants to said reaction vessel to create a solution comprising a bottom solution surface and a top solution surface; and applying heat to said bottom solution surface with said heat source and cooling said top solution surface with active or passive cooling means under such conditions that a temperature differential of at least 5 degrees Celsius is established between said bottom solution surface and said top solution surface and a convection cell is established (col. 4, lines 27-42; col. 5-6; and especially Example 3, col. 18, beginning at line 34 to col. 19, line 38).

Regarding claims 2-4 and 15-17, Burns et al teach the method of claim 1 and 14 as previously described above. Burns et al teach that the method and device can be used in a variety of chemical and biological reactions, including nucleic acid amplification (col. 4, lines 6-

26). Burns further teach discloses in Figure 7, wherein results (products) were analyzed from nucleic acid amplification via PCR (see Example 5). Therefore, a nucleic acid comprising a target and primer substantially homologous to at least a portion of said target are inherent in the teaching of the nucleic acid amplification reaction via PCR.

Regarding claims 5 and 18, Burns et al teach the method of claims 1 and 14, wherein said reaction vessel comprises at least silicones (col. 5, lines 20-33).

Regarding claim 6 and 19, Burns et al teach the method of claim 1 and 14, wherein said reaction vessel is part of an array (figure 5, col. 4, lines 56-66).

Regarding claim 7 and 20, Burns et al teach the method of claims 1 and 14, wherein a temperature differential of at least 10 degrees Celsius is established between said bottom solution surface and said top solution surface and a convection cell is established (col. 19, line 25-38). Note\* the reference teaches wherein the temperature difference between the top and bottom solutions are between 35 and 40 degrees Celsius.

Regarding claim 8 and 21, Burns et al teach the method of claims 1 and 14, also providing at least one microdroplet channel, wherein said microdroplet channel is in fluid communication with said reaction vessel (Abstract).

Regarding claim 22, Burns et al teach a method comprising providing a reaction vessel configured with a width of about 1 mm and a height of about less than about 10 times said width; a heat source, a cooling means and reactants; introducing said reactants to said reaction vessel to create a solution comprising a bottom solution surface and a top solution surface; and applying heat to said bottom solution surface with said heat source and cooling said top solution surface with active or passive cooling means under such conditions that a temperature differential of at

least 5 degrees Celsius is established between said bottom solution surface and said top solution surface and a convection cell is established (col. 4, lines 27-42; col. 5-6; and especially Example 3, col. 18, beginning at line 34 to col. 19, line 38). Note\* the reference teaches at col. 6, lines 51-65, that the channel volume are based on the channel length (height), which is approximately between 1 and 100 nanoliters.

Regarding claims 23 and 24, Burns et teach the reaction vessel of claim 22, wherein in cross sections of the reaction vessel, the structure appears to have portions that are curved and portions with corners (see Figures 1, 3, 4 and especially Figure 5).

Regarding claim, 24, Burns teach the reaction vessel of claim 22, wherein in cross section the reaction vessel is with corners (see Figures, especially figure 5).

Regarding claims 25-27, Burns et al teach the method of claim 22 as previously described above. Burns et al teach that the method and device can be used in a variety of chemical and biological reactions, including nucleic acid amplification (col. 4, lines 6-26). Burns further teach discloses in Figure 7, wherein results (products) were analyzed from nucleic acid amplification via PCR (see Example 5). Therefore, a nucleic acid comprising a target and primer substantially homologous to a least a portion of said target are inherent in the teaching of the nucleic acid amplification reaction via PCR.

Regarding claim 28, Burns et al teach the method of claim 22, wherein said reaction vessel comprises at least silicones (col. 5, lines 20-33).

Regarding claim 30, Burns et al teach the method of claim 22, wherein a temperature differential of at least 10 degrees Celsius is established between said bottom solution surface and said top solution surface and a convection cell is established (col. 19, line 25-38). Note\* the reference teaches wherein the temperature difference between the top and bottom solutions are between 35 and 40 degrees Celsius.

Regarding claim 31, Burns et al teach the method of claim 22, also providing at least one microdroplet channel, wherein said microdroplet channel is in fluid communication with said reaction vessel (Abstract). Therefore, Burns et al meets the limitations of claims 1-8 and 14-31 of the instant invention.

***Prior art made of Record***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Krishnan et al (Science, vol. 298, page 793, October 25, 2002) teach PCR amplification in a Rayleigh-Benard convection cell.

***Conclusion***

8. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to [cynthia.wilder@uspto.gov](mailto:cynthia.wilder@uspto.gov). Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1637

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
CYNTHIA WILDER  
PATENT EXAMINER

12/6/2005